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10/623,200

07/18/2003

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07/26/2006

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,200

Applicant(s)

OSYPKA, THOMAS P.

Examiner

Kristen Mullen

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/12/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

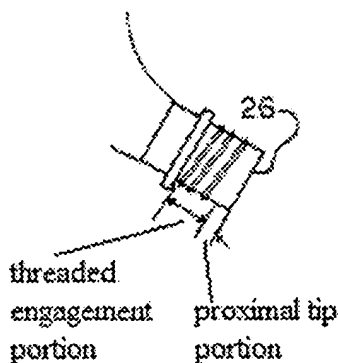
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Xavier (5,458,631).

Regarding claim 3, Xavier shows an elongated lead body (12) having opposed proximal and distal end portions and having at least one lumen (17) extending therethrough; an electrode assembly (14) operatively associated with the distal end portion of the lead body; a connector assembly operatively associated with the proximal end portion of the lead body, the connector assembly having an engagement stem (26) depending therefrom, the engagement stem having the at least one lumen of the lead body extending therethrough, and including a proximal tip portion and threaded engagement portion distal to the proximal tip portion (See picture below)



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and a detachable ported connector fitting (36, 34) having a body with an engagement bore, the engagement bore having a proximal receiving section configured to receive the proximal tip portion of the engagement stem and a threaded engaging section distal to the proximal receiving section of the bore configured to engage the threaded engagement portion of the engagement stem, and having at least one passageway extending therethrough, in communication with the engagement bore (Col. 6, line 10-44; Figs. 1-2).

Regarding claim 5, Xavier shows at least one lumen (17) formed in the lead body has an outlet port (30) at the distal end of the lead body (Fig. 2).

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clemens et al. (2002/0077684) in view of Westlund et al. (2002/0077683).

Regarding claim 1, Clemens shows an elongated lead body having opposed proximal and distal end portions and having at least one lumen extending therethrough; an electrode assembly (16) operatively associated with the distal end portion of the lead body; a connector assembly (50) operatively associated with the proximal end portion of the lead body, the connector assembly having an engagement stem (54) depending therefrom the engagement stem having at

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least one lumen of the lead body extending therethrough and including a proximal tip portion and a detachable ported connector fitting (58) having a body with an engagement bore the engagement section having a proximal receiving section configured to receive the proximal tip portion of the engagement stem and having at least one passageway (104) extending therethrough, in communication with the engagement bore (Fig. 1).

Although Clemens shows a connector assembly with an engagement stem (54) and ported connector with an engagement bore, and it isn't clear how they are coupled, Clemens fails to specifically show the engagement stem and engagement bore are threaded. Attention is directed to Westlund who shows a similar connector assembly (860) and ported connector (820) that utilizes threads for coupling the connector assembly and ported connector (Fig. 9). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ threads on the engagement stem and engagement bore for the coupling of the engagement stem and engagement bore of Clemens wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Clemens device. MPEP 2144.06, *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).

With respect to claim 2, Clemens shows the ported connector fitting (58) has a bifurcated body that includes a first portion having a first passageway extending therethrough (60), in communication with the engagement bore, and a second portion having a second passageway (61) extending therethrough, in communication with the engagement bore (Fig. 1).

Regarding claim 4, Clemens shows at least one passageway formed in the ported connector (58) fitting has a funnel-shaped inlet region (where stylet assembly 62 is introduced).

With respect to claims 5-6, Clemens shows at least one lumen (114) formed in the lead body has an outlet port at the distal end of the lead body and at least one lumen (104) formed in the lead body has an outlet port (102) at a location spaced from the distal end of the lead body (Fig. 2).

Regarding claim 7, Clemens shows the electrode assembly is bipolar and includes a distal tip electrode (16) and a proximal ring electrode (20) (Fig. 2).

With respect to claim 8, Clemens shows a helical conductor coil (138, 140) extending through the lead body for connecting the electrode assembly with the connector assembly (para. [0047]).

Regarding claim 9, Clemens discloses a helical fixation screw operatively associated with the distal end of the lead body for actively securing the lead to cardiac tissue (Col. 7, line 46-51).

With respect to claim 10, Clemens shows a plurality of flexible tines (162) provided at the distal end of the lead body.

The statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Response to Arguments

5. Applicant's arguments filed 5/18/06 have been fully considered but they are not persuasive.

6. In response to applicant's arguments asserting that Xavier does not disclose a detachable ported connector, the examiner points out that the detachable ported connector is represented by elements 34, 36 in the Xavier reference.

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7. Applicant's arguments with respect to the previous rejections of claims 1-2 and 4-10 based on Clemens alone have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

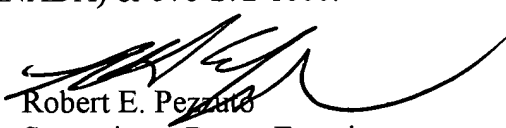
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



kdm



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766